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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,389	12/13/2005	Michael J. Palmowski	0380-P03220US1	2535

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DANN, DORFMAN, HERRELL & SKILLMAN
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EXAMINER	
BLUMEL, BENJAMIN P	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,389	PALMOWSKI ET AL.	
	Examiner	Art Unit	
	BENJAMIN P. BLUMEL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30 and 38-45* is/are pending in the application.

4a) Of the above claim(s) *3-6,8,9,11,12,15-30,38 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,10,13,14,39-41 and 43-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

This application contains claims 3-6, 8, 9, 11, 12, 15-30, 38 and 42 are drawn to an invention nonelected with traverse in the reply filed on 1/22/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are examined on the merits.

Response to Arguments

Applicant's arguments filed 9/24/2010 have been fully considered but they are not persuasive. See responses below.

Priority

Based on applicant's arguments, the foreign priority of the present invention is that of US Provisional Application 60/478,623, which was filed on June 13, 2003.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(Prior Rejection Maintained) Claims 1, 2, 7, 10, 13, 14, 39-41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casimiro et al. (Journal of Virology, 2003), Hill et al. (US PGPub 2003/0138454) and Lewis et al. (Journal of Virology, 2001).

The claimed invention is drawn to a method of stimulating an immune response to an antigen in an individual by a heterologous prime-boost immunization protocol, the method comprising the steps of:

i) administering to the individual a plasmid or other expression vector, which encodes said antigen to prime said immune response;

ii) administering to the individual a lentivirus engineered to comprise exogenous nucleic acid encoding said antigen to boost the primed immune response. The exogenous nucleic acid encodes a pathogen-derived antigen, such as a lentiviral antigen. The claimed invention also includes a method of administering lentivirus particles, which encode said antigen, to an individual in order to boost a pre-existing immune response that was elicited by the administration of a nucleic acid also encoding said antigen. However, for purposes of examination, this alternative method involving the boosting of a pre-existing immune response is interpreted to be within the same scope as that of the prime/boost method of claim 1. The lentivirus is infectious but replication-deficient.

Casimiro et al. teach the development of a prime-boost immunization protocol for inducing an immune response to HIV-1 gag. Casimiro et al. employed a heterologous

prime boost system in which DNA encoding the gene is administered to macaques followed by infectious, replication deficient Adenovirus serotype 5 being administered that also encodes the gag gene. Casimiro et al. observed an increase is peripheral blood mononuclear cells after the boost administration relative to the priming dosage. Casimiro et al. also observed an increase in CD8+ T cells producing IFN-y. However, Casimiro et al. do not teach the use of an infectious, replication deficient lentivirus engineered to encode an exogenous nucleic acid sequence of an antigen. See pages 6306 and figures 6 and 7.

Hill et al. teach the development of a heterologous prime-boost immunization protocol. Hill et al. use DNA or proteins of the antigen of interest (priming) followed by a replication deficient poxvirus that encodes the antigen of interest. One specific antigen that Hill et al. focus on is that of HIV envelope antigens. However, Hill et al. do not teach the use of an infectious, replication deficient lentivirus engineered to encode an exogenous nucleic acid sequence of an antigen. See paragraphs 11, 12, 28, 30-33.

Lewis et al. teach the development of an infectious, replication deficient lentivirus vector. See page 9340.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Casimiro et al. and Hill et al. in order to use lentivirus that is infectious but can't replicate in a heterologous prime-boost method. One would have been motivated to do so, given the suggestion by Casimiro et al. and Hill et al. that the method be used to improve immune responses to HIV proteins via a heterologous prime-boost immunization protocol that relies on DNA encoding the protein and a replication deficient virus. There would have been a reasonable expectation of success, given the

knowledge that recombinant replication deficient, infectious lentiviruses can be generated and can express exogenous proteins, such as GFP, as taught by Lewis et al. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Response to arguments:

The Examiner admits that Casimiro et al. and Hill et al. do not teach the use of an infectious, replication-defective lentivirus vector. Furthermore, while Casimiro et al. and Hill et al. teach heterologous prime-boost immunization methods focusing on increasing immune responses against HIV genes/proteins, they state that infectious, replication defective Adenovirus 5 or MVA, respectively, must be used in their immunization protocols based on the improved immune responses being generated. In other words, neither Hill et al. or Casimiro et al. provide any motivation to change their infectious, replication-deficient viral vectors in the disclosed prime-boost immunization protocols. This is therefore interpreted as a clear teach away from using any other viral system besides adenovirus type 5 or poxvirus. The applicants also argue that the Examiner has also used impermissible hindsight in establishing the obviousness of the claimed invention. In addition, Lewis et al. do not teach or suggest the use of their lentivirus vector in any type of a method for inducing an immune response.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of

ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response, the MPEP states at section 2123 (II):

[Disclosed examples and preferred embodiments **do not constitute a teaching away from a broader disclosure or nonpreferred embodiments**. In re Susi,440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994) (**The invention was directed to an epoxy impregnated fiber-reinforced printed circuit material**. The applied prior art reference taught a printed circuit material similar to that of the claims **but impregnated with polyester-imide resin instead of epoxy**. **The reference, however, disclosed that epoxy was known for this use**, but that epoxy impregnated circuit boards have "relatively acceptable dimensional stability" and "some degree of flexibility," **but are inferior to circuit boards impregnated with polyester-imide resins**. The court upheld the rejection concluding that applicant's argument that the reference teaches away from using epoxy was insufficient to overcome the rejection since "Gurley asserted no discovery beyond what was known in the art." 27 F.3d at 554, 31 USPQ2d at 1132.). Furthermore, "[t]he prior art's mere disclosure of more than one alternative].

Therefore, while the specific uses of infectious, replication defective Adenovirus type 5 or MVA in a prime boost immunization method is preferred, as taught by Casimiro et al. and Hill et al., this does not constitute teaching away.

With regard to Lewis et al., MPEP 2144.06 [**Art Recognized Equivalence for the Same Purpose] :** II.< SUBSTITUTING EQUIVALENTS KNOWN FOR THE SAME PURPOSE, permits that any infectious, replication defective viral vector capable of expressing a heterologous gene, can be substituted for another viral vector that also expresses a heterologous gene. As a result, the infectious, replication defective lentivirus vector of Lewis et al. is a functional equivalent of the infectious, replication defective Adenovirus type 5 and MVA of Casimiro et al. and Hill et al., respectively. Therefore,

one of ordinary skill in the art would be motivated and also have a reasonable expectation of success at replacing these adenovirus and MVA vectors with the lentivirus of Lewis et al. for use in a heterologous prime-boost immunization protocol.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BO PENG/
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/
Examiner
Art Unit 1648